UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF NEW YORK

BAUSCH & LOMB INCORPORATED, Plaintiff, v. MIMETOGEN PHARMACEUTICALS, INC., Defendant.	Civil Action No. 14-CV-6640-FPG **ANSWER WITH COUNTERCLAIMS AND THIRD PARTY CLAIMS**
MIMETOGEN PHARMACEUTICALS INC., Counterclaim Plaintiff, v. BAUSCH & LOMB INCORPORATED, Counterclaim Defendant, and VALEANT PHARMACEUTICALS INTERNATIONAL, INC., Third Party Defendant.	

Defendant, Mimetogen Pharmaceuticals Inc. ("MPI", "Defendant," or "Counterclaim Plaintiff"), by and through its attorneys, Shlansky Law Group, LLP, submits the following Answer with Counterclaims against Bausch & Lomb Incorporated ("B+L") and Third-Party claims against Valeant Pharmaceuticals International, Inc. ("Valeant").

ANSWER

1. MPI lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore, they are denied.

2. Admitted.

3. Denied. The allegations set forth in this paragraph constitute legal conclusions to which no response is required and same are deemed denied.

4. Denied. The allegations set forth in this paragraph constitute legal conclusions to which no response is required and same are deemed denied.

5. Admitted.

6. Denied. The Agreement is a writing which speaks for itself, and Defendant refers to the writing itself for a complete and accurate assessment of its content and denies any characterizations as to the content.

7. Admitted.

8. Denied. The Agreement is a writing which speaks for itself, and Defendant refers to the writing itself for a complete and accurate assessment of its content and denies any characterizations as to the content.

9. Denied. The Agreement is a writing which speaks for itself, and Defendant refers to the writing itself for a complete and accurate assessment of its content and denies any characterizations as to the content.

10. Denied. The Agreement is a writing which speaks for itself, and Defendant refers to the writing itself for a complete and accurate assessment of its contents and denies any characterizations as to the content.

11. Denied. The Agreement is a writing which speaks for itself, and Defendant refers to the writing itself for a complete and accurate assessment of its content and denies any characterizations as to the content.

12. Admitted.

13. Denied. MPI denies that the results of the Initial Phase III Trial were "Not Successful." MPI also denies B+L has ever "believed" that the results of the Initial Phase III Trial were "Not Successful" as that term is defined in the Agreement.

14. Admitted.

15. Denied. The correspondence from B+L dated August 29, 2014 is a writing which speaks for itself, and the allegations regarding its contents set forth in this paragraph are denied, including the date on which any such notice was provided to Mimetogen and any factual or legal contentions contained therein.

16. Admitted.

17. Defendant repeats, realleges, and incorporates the responses contained in the foregoing paragraphs.

18. Denied. The allegations set forth in this paragraph constitute legal conclusions to which no response is required and same are deemed denied.

19. Denied. The allegations contained in this paragraph are denied as stated, and the accompanying Affirmative Defenses, Counterclaims, and Third Party Claims asserted against B+L and Valeant are incorporated herein by reference as though set forth in full.

20. Denied. The allegations set forth in this paragraph constitute legal conclusions as to which no response is required and same are deemed denied.

AFFIRMATIVE DEFENSES

FIRST AFFIRMATIVE DEFENSE

21. Plaintiff has failed to state a claim on which relief may be granted.

SECOND AFFIRMATIVE DEFENSE

22. One or more of Plaintiff's claims are barred by the doctrine of unclean hands.

THIRD AFFIRMATIVE DEFENSE

23. Plaintiff has suffered no harm.

FOURTH AFFIRMATIVE DEFENSE

24. Defendant reserves the right to rely upon other affirmative defenses that may become evident during the pendency of this suit and to amend its responses to Plaintiff's complaint to assert any such additional affirmative defenses.

COUNTERCLAIMS AND THIRD PARTY CLAIMS

Defendant/Counterclaim Plaintiff MPI asserts the following Counterclaims against Plaintiff/Counterclaim Defendant, B+L, and Third Party Claims Against Third Party Defendant Valeant, a Canadian corporation and the parent company of B+L, as described in ¶ 19. In support of its claims, Counterclaim Plaintiff alleges as follows:

INTRODUCTION

1. MPI brings its Counterclaims and Third Party Claims against B+L and Valeant for: (i) B+L's breach of a Development Collaboration and Exclusive Option Agreement (the "Agreement") dated July 17, 2013; (ii) B+L's intentional breach of contract; (iii) intentional interference with contract by Valeant; and (iv) Valeant's violations of § 11 of Mass. Gen. L. c. 93A for unfair and deceptive acts and practices under Massachusetts law.

2. Under the terms of the Agreement, MPI granted B+L an exclusive option (the

"Option") to obtain the rights to develop and commercialize MPI's proprietary MIM-D3 ophthalmic solution for the treatment of dry eye syndrome (the "Product"), a potential first-in-class therapy with an estimated domestic market space worth $3 billion.

3. The Agreement set out a carefully-negotiated structure and process for funding the clinical trials and the exercise of the Option based on the results of the initial clinical trial (referred to in the Agreement as the "Initial Phase III Trial"), and, as necessary, subsequent Phase III clinical trials (the "Additional Trials").

4. The parties recognized and contemplated in the Agreement that the Initial Phase III Trial would most likely have to be followed by three Additional Trials.

5. The Agreement sets forth a detailed description of potential clinical trial outcomes and the contractual obligations of the parties in light of each of those outcomes.

6. The Agreement provides for funding of the Initial Phase III Trial. If the Initial Phase III Trial was either "Completely Successful" or "Successful" (each as defined in the Agreement as set forth below), B+L was obligated to exercise the Option and pay the exercise fee.

7. If the Initial Phase III Trial was "Not Successful" (as defined in the Agreement), B+L could decline to exercise or extend the Option and terminate its obligation to fund Additional Trials under the Agreement.

8. If the Initial Phase III Trial was neither "Completely Successful" nor "Successful," B+L could exercise the Option, extend the Option by funding an Additional Trial, or allow the Option to expire. If B+L allowed the Option to expire, unless the initial trial was "Not Successful" it agreed to pay an amount, which amount could, among other things, assist in the funding of the next clinical trial and allow MPI continue carrying on the development of

MIM-D3.

9. In particular, § 5.5(c) of the Agreement provides that B+L is obligated to pay $20 million dollars to MPI where the Initial Phase III Trial was "Inconclusive" and B+L does not exercise or extend the Option. The Initial Phase III Trial results, in fact, were "Inconclusive," and B+L did not exercise or extend the Option.

10. The Option expired on August 31, 2014, without any notice from B+L within that timeframe, but B+L has failed and refused to pay the $20 million due under the Agreement, by knowingly and falsely claiming that the results of the Initial Phase III Trial were "Not Successful."

11. Immediately prior to falsely claiming that the results of the Initial Phase III Trial were not "Not Successful," B+L actively participated in planning and preparing for the First Additional Trial.

12. On April 22, 2014, Valeant, the parent company of B+L, announced that it was seeking to acquire Allergan, Inc. ("Allergan") the manufacturer of the only FDA-approved drug for dry eye syndrome, Restasis®.

13. If Valeant was successful in acquiring Allergan, Valeant would have no need for MIM-D3 in its product portfolio, and a disincentive to see Additional Trials funded for a late-stage product competitive with Restasis®.

14. MPI released the results and data from the Initial Phase III Trial to B+L on May 12, 2014.

15. At the end of August 2014, when Valeant's acquisition of Allergan appeared to be growing imminent and B+L was required to exercise, extend, or terminate the Option and pay the $20 million termination fee to MPI, B+L reversed its position and falsely claimed that the

Initial Phase III Trial was "Not Successful."

THE PARTIES

16. Defendant/Counterclaim Plaintiff Mimetogen Pharmaceuticals Inc. is a privately-held biotechnology company incorporated in Quebec, Canada, with a principal place of business at 1000 de la Gauchetière Street West, Suite 900, Montreal, Quebec, Canada H3B 5H4. MPI focuses on developing the use of peptidomimetics as a novel approach to treating ophthalmic diseases with high unmet medical needs. The company is currently developing novel therapeutic approaches for indications including dry eye syndrome, glaucoma, and other degenerative diseases of the retina.

17. MPI has a wholly-owned subsidiary, Mimetogen Pharmaceuticals USA, Inc. ("MPI USA") with a principal place of business in Gloucester, Massachusetts. MPI USA was the Sponsor/Applicant for the Initial Phase III Trial. MPI regularly conducts business in the Commonwealth of Massachusetts directly and through its subsidiary.

18. Plaintiff/Counterclaim Defendant B+L is incorporated in New York, with a principal place of business at 700 Route 202/206 North, Bridgewater, New Jersey 08807. B+L was acquired by Valeant on August 5, 2013 and continues to operate as a wholly-owned subsidiary of Valeant.

19. Third Party Defendant Valeant is a Canadian corporation, with a principal place of business at 2150 St. Elzéar Blvd. West, Laval, Quebec H7L 4A8. Valeant's United States headquarters are located at 400 Somerset Corporate Boulevard, Bridgewater, New Jersey. Valeant manufactures and markets pharmaceuticals, over-the-counter products, and medical devices in the areas of eye health, dermatology, and neurology therapeutic classes worldwide.

20. Valeant is notorious in the pharmaceutical industry for acquiring pharmaceutical

companies and aggressively slashing research and development expenses post-acquisition. In the past few years, in addition to B+L, Valeant acquired Solta Holdings Inc., Obagi Medical Products, Inc., Medicis Pharmaceutical, and made an unsuccessful attempt to acquire Allergan, Inc.

JURISDICTION AND VENUE

21. This Court has jurisdiction over the dispute between B+L and MPI pursuant to 28 U.S.C. § 1332(a), as the matter is between a citizen of a State and a citizen or subject of a foreign state, and the controversy exceeds the sum or value of $75,000, exclusive of interest and costs.

22. This Court has supplemental jurisdiction over MPI's claims against Valeant pursuant to 28 U.S.C. § 1367(a) because this claim is so related to the claim brought by B+L against MPI in this action that they form part of the same case or controversy.

FACTUAL BACKGROUND

The Development Collaboration and Exclusive Option Agreement

23. MPI is developing a proprietary compound, called MIM-D3 (the "MIM-D3 Technology"), for the treatment of dry eye syndrome. Dry eye syndrome occurs when the eye does not produce enough tears, or when the tears are not of the correct consistency and evaporate too quickly. Inflammation of the surface of the eye may also occur. If left untreated, the condition can lead to pain, ulcers, or scars on the cornea, and, while uncommon, some loss of vision. Dry eye can also have a significant impact on quality of life, making it more difficult to perform activities such as using a computer or reading for an extended period of time.

24. The Initial Phase III Trial was largely conducted in Massachusetts.

25. Under the Agreement, MPI granted B+L the Option to obtain an exclusive, worldwide license and the rights to develop and commercialize the MIM-D3 Technology.

26. B+L paid an initial amount to MPI for the Option on the rights to the MIM-D3 Technology and to assist in the conduct of the Initial Phase III Trial of the MIM-D3 Technology, and agreed under certain parameters to make additional payments. Agreement, §§ 5.1, 5.3.

27. The Agreement provided that the results of the Initial Phase III Trial would determine the alternatives available to B+L for the exercise of the Option. Agreement, § 5.4. In light of the prior results of other clinical trials for dry eye syndrome, the parties recognized that Additional Trials beyond the Initial Phase III Trial would most likely be necessary. Accordingly, the Agreement sets out the terms and conditions under which up to three Additional Trials could proceed.

28. MPI and B+L specified in the Agreement a host of possible trial results and the consequences of those results on the rights and obligations of the parties under the Agreement. As defined in the Agreement, the Initial Phase III Trial results would fall under one of the following categories: "Completely Successful," "Successful," "Partially Successful," "Inconclusive," or "Not Successful." Agreement, § 5.4. The category encompassing those initial clinical trial results then governed the parties' next steps under the Agreement.

29. **"Completely Successful"** was defined in § 1.11 of the Agreement as:

> [T]he results of the Initial Phase III Trial or any Additional Trial indicate that (a) the efficacy of the Licensed Product on both primary sign and symptom endpoints, at the primary time point (Day 29 for the Initial Phase III Trial), as defined in the Protocol, is statistically significantly superior to the vehicle with a p value of 0.050 or less, and (b) following a formal meeting with the FDA, the FDA agrees, per its formal, final meeting minutes, that the Initial Phase III Trial or such Additional Trial is the final study required for the Approval of the Licensed Product.

30. **"Successful"** was defined in § 1.53 of the Agreement as:

> [T]he results of the Initial Phase III Trial or any Additional Trial indicate that (a) the efficacy of the Licensed Product on both primary sign and symptom endpoints, at the primary time point (Day 29 for the Initial Phase

III Trial), as defined in the Protocol, is statistically significantly superior to the vehicle with a p value of 0.050 or less, and (b) following a formal meeting with the FDA, the FDA agrees, per its formal, final meeting minutes, that there are no Significant Safety Issues and that only one additional Phase III Trial is required for Approval. The requirement for the formal meeting with FDA would be waived if both B+L and MP agree that it is not necessary.

31. If the Initial Phase III Trial results were "Completely Successful" or "Successful," B+L was obligated to exercise the Option. Agreement, § 5.4.

32. **"Not Successful"** was defined in § 1.41 of the Agreement as:

> (a) the FDA determines, after a formal meeting and per its formal meeting minutes, that there are Significant Safety Issues, or (b) the results of the Initial Phase III Trial or any Additional Trial indicate that the efficacy of the Licensed Product on both primary sign and symptom endpoints at the primary time point (Day 29 for the Initial Phase III Trial), as defined in the Protocol, are not statistically significantly superior to the vehicle with a p value of 0.050 or less, and the FDA does not agree that either a sign or a symptom, that were assessed in the Initial Phase III Trial or the Additional Trial, can be used as the primary sign or symptom to support the Approval of the Licensed Product.

33. **"Partially Successful"** was defined in § 1.45 of the Agreement as:

> [T]he results of the Initial Phase III Trial or any Additional Trial indicate that (a) the efficacy of the Licensed Product on either or both primary sign and symptom endpoints, at the primary time point (Day 29 for the Initial Phase III Trial), as defined in the Protocol, is not statistically significantly superior to the vehicle with a p value of 0.050 or less, and (b) following a formal meeting with the FDA, the FDA agrees, per its formal, final meeting minutes, that there are no Significant Safety Issues and that only one additional Phase III Trial is required for Approval.

34. **"Inconclusive"** was defined in § 1.25 of the Agreement as:

> [T]he results of the Initial Phase III Trial or any Additional Trial are not Completely Successful, Successful, Partially Successful or Not Successful.

35. If the Initial Phase III Trial results were "Not Successful," B+L had no obligation to exercise or extend the Option and no obligation to pay a termination fee. Agreement, §§ 5.4, 5.5(c).

36. If the Initial Phase III Trial results were "Partially Successful" or "Inconclusive," B+L had the right to extend the Option, in which case it was obligated to pay for up to $15 million of clinical trial costs for an Additional Trial, plus half of the costs of the trial over $15 million. Agreement, § 5.6(e). It then retained its rights to the Option, which were further defined in the Agreement based on the results of the next trial.

37. Alternatively, where the trial results were either "Partially Successful" or "Inconclusive," B+L could decide not to exercise or extend the Option, but in that case B+L was obligated to make a non-refundable payment of $20 million to MPI:

> If . . . the Initial Phase III Trial results are Partially Successful or Inconclusive, and B+L, in its sole discretion, has neither exercised nor extended the Option by the end of the Option Period, B+L will make a non-refundable payment to MP of Twenty Million U.S. Dollars (U.S. $20,000,000), payable within thirty (30) days of the earlier of (x) B+L's written notice to MP of its election not to exercise the Option or (y) the end of the Option Period.

Agreement, § 5.5(c).

38. The $20 million payment was understood by the parties to be made to, among other things, assist in the funding of the next clinical trial and allow MPI to continue the development of MIM-D3 without delay or interruption.

39. It was contemplated by the parties that MPI would suffer damages in the form of loss of some or all of the value of its entire enterprise if B+L walked away from the Agreement after release of the Initial Phase III Trial results and publicly expressed a belief that the results were "Not Successful."

40. MPI had a *bona fide* proposal from a venture capital fund to fund the Initial Trial. However, MPI entered into the collaboration with B+L since, unless the drug showed safety issues or there was no pathway to approval through the primary or exploratory endpoints from

the Initial Phase III Trial, there was a guarantee of funding the Initial Phase III Trial and one Additional Trial, either through B+L extending the Option or through the $20 million termination payment.

The Initial Phase III Trial

41. On October 10, 2013, MPI announced that it had enrolled the initial patients in the Initial Phase III Trial.

42. MPI conducted a 403-patient 8-week Phase III clinical trial with an ophthalmic solution containing MIM-D3.

43. Patients were divided into two groups: (i) the active drug group who received the Product; and (ii) the placebo group who received only a placebo. The trial involved a specialized chamber, called the Controlled Adverse Environment chamber ("CAE chamber"), which subjected participants' eyes to a stressful, drying environment.

44. The Initial Phase III Trial compared the active drug group's ability to withstand this drying environment to the placebo group's ability. Specifically, MPI measured the change between participants' central and total corneal fluorescein staining before they entered the CAE chamber and their central and total corneal fluorescein staining after they experienced the chamber. By comparing the change experienced by the active drug group to the change experienced by the placebo group, MPI was able to gain information on the Product's safety and efficacy.

45. MPI also used participants' responses to an industry questionnaire, the Ocular Surface Disease Index ("OSDI"), to determine whether the Product improved common vision-related symptoms of dry eye syndrome. MPI measured the change in participants' responses to

questions about their eye health and abilities throughout the course of the study, collecting these data for both the active drug group and the placebo group.

46. As set forth in the Protocol for the Initial Phase III Trial, two of the endpoints assessed by the Initial Phase III Trial were: (1) the change in participants' central and total corneal fluorescein staining following exposure to the CAE chamber (the sign measurements); and (2) the change in participants' responses about their condition in the OSDI questionnaire (the symptom measurements). The Protocol is attached as Exhibit B to the Agreement.

47. The Initial Phase III Trial was conducted in large part in Massachusetts, either at a private ophthalmology clinic in Quincy, Massachusetts or in Andover, Massachusetts at the facilities belonging to Ora, Inc., a clinical research organization retained to manage the MIM-D3 clinical trials. Similarly, all Additional Trials were to use clinics in Massachusetts and be run by Ora, Inc.

48. After the conclusion of the Initial Phase III Trial, B+L was provided with the results on May 12, 2014. During an April 25, 2014 conversation between MPI and B+L representatives, B+L's representative declined the opportunity for B+L to receive an early look at the results of the data generated during the Initial Phase III Trial, explaining that reviewing the trial results prior to the scheduled May 12, 2014 meeting with MPI would force B+L to meet earlier than scheduled with Valeant executive management on May 19, 2014 to discuss how B+L should proceed under the Agreement.

49. The members of B+L's team were enthusiastic about the results of the Initial Phase III Trial during the late May/early June 2014 timeframe. In early June 2014, the head of product manufacturing for B+L, traveled to Germany to perform an audit of the manufacturing process for new batches of MIM-D3 to be used in Additional Trials.

50. During this time, the B+L development team and MPI had bi-weekly standing meeting calls to discuss all aspects of the development of MIM-D3, including regulatory, Chemistry Manufacturing Controls, production of the clinical trial materials for the First Additional Trial, budget and all other related MIM-D3 matters. On August 13, 2014, the last standing meeting call occurred and approximately 10 B+L employees participated.

51. During this time, B+L also participated in preparing the FDA meeting materials and the design study for Additional Trials.

FDA Meeting and Meeting Minutes

52. On July 15, 2014, representatives from MPI and B+L met with FDA officials to review the Initial Phase III Trial results. As stated in the cover letter from the FDA with the minutes of that meeting: "The purpose of the meeting was to discuss the recently completed Phase 3 study data and to discuss potential clinical development pathways for the evaluation of MIM-D3 ophthalmic solution as a treatment for dry eye."

53. The parties agree that the Initial Phase III Trial did not meet the definition and criteria for "Completely Successful," "Successful," or "Partially Successful" based on the primary sign and symptom endpoints defined in the Protocol.

54. Based in part on the results of the Initial Phase III Trial, the FDA was asked in the July 15, 2014 meeting whether other specific sign and symptom measures assessed in the initial trial (listed as Exploratory Efficacy Measures on page 8 of the Protocol) could be used as primary sign or symptom endpoints in support of FDA approval of the Product in Additional Trials.

55. The Exploratory Efficacy Measures had, in fact, been measured and assessed as exploratory sign and symptom endpoints in the Initial Phase III Trial.

56. B+L was provided the list of proposed draft questions well in advance of the FDA Meeting and was allowed to comment on and participate in the preparation of those questions.

57. B+L was fully aware that the questions drafted and submitted to the FDA were directed to the approval of the exploratory endpoints that had been assessed in the Initial Phase III Trial, because those endpoints had generated positive indications during the trial.

58. B+L also was aware that the questions posed to the FDA mirrored the language in the "Not Successful" definition in the Agreement such that, if the FDA approved the use of the exploratory endpoints for an Additional Trial, the Initial Phase III Trial results would not be "Not Successful."

59. On July 30, 2014, the FDA circulated the Minutes from the July 15, 2014 Meeting. These Meeting minutes included the FDA's responses to the questions submitted by MPI.

60. One of the questions posed to the FDA was whether the change in participants' central fluorescein staining following exposure to the CAE chamber would be acceptable as a "primary sign endpoint" in support of the FDA's approval of the Product.

61. The FDA responded as follows:

> A change in corneal fluorescein staining in a pre-specified area (e.g., central region) at a pre-specified time following exposure to a dry environment is acceptable as a "sign endpoint" when coupled with a "symptom endpoint" to support the efficacy of a product for the treatment of dry eyes.

62. MPI asked an identical question regarding the acceptability of the change in participants' fluorescein staining in the total cornea (sum of the inferior, central and superior regions) as a sign endpoint and received an identical affirmative response from the FDA.

63. Another question posed by MPI was whether the change in participants' responses to the OSDI questionnaire could be used as a "primary symptom endpoint" in support of the FDA's approval of the Product. The FDA responded that:

> A change in a patient's response to a question about an ocular symptom at a pre-specified time is acceptable as a "symptom endpoint" when coupled with a "sign endpoint" to support the efficacy of a product for the treatment of dry eyes.

64. In sum, the final FDA Meeting Minutes confirmed that sign and symptom endpoints assessed during the Initial Phase III Trial, namely the change in participants' central and total fluorescein staining following exposure to the CAE chamber, and the change in participants' responses to the OSDI questionnaire, can be used as the primary sign and symptom endpoints to support approval of the Product.

65. The definition of "Not Successful" in the Agreement is, in relevant part, that: "the FDA does not agree that either a sign or a symptom, that were assessed in the Initial Phase III Trial or the Additional Trial, can be used as the primary sign or symptom to support the Approval of the Licensed Product." Agreement, § 1.41.

66. In other words, to avoid falling under the definition of "Not Successful" in the Agreement, the FDA had to agree that either a sign or symptom endpoint assessed in the Initial Phase III Trial or an Additional Trial can be used as the primary sign or symptom to support the Approval of the Licensed Product.

67. As reflected in the final FDA Meeting Minutes, the FDA agreed that both a sign and a symptom assessed in the Initial Phase III Trial can be used as the primary sign or symptom endpoints to support the Approval of the Licensed Product.

68. There is no dispute that the FDA expressed no safety issues with the Product based on the results of the Initial Phase III Trial.

69. The final FDA Meeting Minutes confirmed that the Initial Phase III Trial results do not fall under the definition of "Not Successful" in § 1.41(b).

70. There is no reasonable possibility that B+L and Valeant, with their expansive and sophisticated knowledge of the pharmaceutical industry, clinical trials, and FDA approval processes, do not know for certain that the outcome of the Initial Phase III Trial is not "Not Successful" pursuant to the carefully crafted language of the Agreement defining that term.

71. Consequently, the Initial Phase III Trial results were "Inconclusive" pursuant to § 1.25 of the Agreement, and B+L's (and Valeant's) contention otherwise is a knowing, transparent falsehood manufactured for ulterior purposes.

Valeant's Acquisition of B+L

72. On May 27, 2013, Valeant announced that it was acquiring B+L in a transaction valued at $8.7 billion. On the day the Valeant/B+L acquisition was announced, B+L sent an e-mail to MPI assuring MPI that it remained committed to closing the transaction with MPI, while offering to arrange a meeting between MPI and Valeant to "provide the assurance and comfort level that we are excited to execute the deal."

73. B+L was compelled to provide this type of assurance to MPI due to Valeant's industry reputation as a serial acquirer of other pharmaceutical companies and its preferred business strategy of aggressively slashing research and development costs at its acquired companies.

74. After the Agreement was entered into by MPI and B+L on July 17, 2013, Valeant completed its acquisition of B+L on August 5, 2013, and B+L became a wholly-owned subsidiary of Valeant.

Valeant's Proposed Acquisition of Allergan, the Manufacturer of the Only FDA-Approved Dry Eye Product and MPI's Competitor

75. Nearly concurrent with the release of the Initial Phase III Trial results, on April 22, 2014, Valeant announced that it was submitting a proposal to acquire Allergan in connection with the activist hedge fund Pershing Square. The Valeant announcement indicated that Pershing Square had just purchased 9.7% of Allergan's common stock (making Pershing Square Allergan's largest stockholder) and strongly supported the transaction proposal made by Valeant for Allergan. Allergan is the maker of Restasis®, which is currently the only FDA approved drug to treat chronic dry eye syndrome.

76. On May 12, 2014, Allergan rejected Valeant's proposed transaction. Valeant responded with a hostile offer for Allergan on May 28, 2014.

77. After litigation in early June 2014 between Allergan and its shareholders over plans by Pershing Square to launch a proxy contest to oust a majority of Allergan's directors not supporting a transaction with Valeant, on June 27, 2014, the parties settled the dispute after Allergan agreed that calling such a special shareholder meeting would not trigger Allergan's shareholders' rights plan, a defensive tactic put in place to prevent a hostile takeover of Allergan by making its stock less attractive to acquire.

78. Subsequently, on July 31, 2014, Valeant issued a presentation regarding its financial results where it showed itself on a stand-alone basis and on a combined basis with Allergan based on Allergan's financial projections.

79. MPI was not mentioned in the July 31, 2014 presentation by Valeant, although Valeant had previously mentioned MPI in its presentations in response to criticism by Allergan regarding Valeant's aggressive slashing of research and development at acquired companies.

80. On August 26, 2014, Allergan and Pershing Square announced that a special shareholder meeting was being set for December 18, 2014, in order for Allergan's shareholders to consider the issue of replacing a majority of Allergan's board in order to facilitate a transaction with Valeant. Earlier in the month of August, more than 30% of Allergan's shareholders called for such a special shareholder meeting.

81. Allergan eventually managed to fend off Valeant and enter into an alternative transaction to sell itself to Actavis plc in a topping bid which was not announced until November 17, 2014, four days after B+L filed the Complaint against MPI.

82. B+L's attitude towards its partnership with MPI and interpretation of the Initial Phase III Trial results began to shift in a negative manner after Valeant announced its pursuit of Allergan, MPI's competitor.

B+L's Breach of the Agreement

83. The final FDA Meeting Minutes were issued to MPI on July 31, 2014. On August 1, 2014, MPI sent the Minutes to B+L. At that time, MPI informed B+L that the final FDA meeting Minutes demonstrated that the results of the Initial Phase III Trial were "Inconclusive," and that B+L had 30 days to exercise or extend the Option, or the Option would expire and trigger the $20 million termination fee under the Agreement.

84. On August 4, 2014, B+L responded with an acknowledgment of receipt of the final FDA Meeting Minutes and commencement of the 30 day period under the Option. B+L also stated that it looked forward to working with MPI to explore the possibility of collaborating with a third party to further develop the Product. In this regard, B+L included a list of proposed third parties for MPI to consider for such a collaboration, which list included Regeneron Pharmaceuticals, Inc.; Shire Plc.; Santen Pharmaceutical Co., Ltd.; Sanofi S.A.; Bayer AG;

GlaxoSmithKline plc.; and "Actavis/Forest." It also expressed appreciation for MPI's willingness to consider proceeding with Additional Trials with a collaborator.

85. However, despite its stated intent to continue working with MPI on further development of the Product, B+L did not exercise or extend the Option by August 31, 2014, and the Option expired. Pursuant to § 5.5(c) of the Agreement, B+L was required to make the $20 million payment to MPI by September 30, 2014.

86. B+L refused to pay the $20 million termination fee and falsely claimed that the results of the Initial Phase III Trial were "Not Successful" as a basis for refusing to tender the $20 million termination fee, despite the fact that the FDA had clearly agreed that the exploratory endpoints assessed by MPI during the Initial Phase III Trial could be used as sign and symptom endpoints to seek FDA approval of the Product in an Additional Trial.

87. B+L's refusal to pay the $20 million termination fee, and its false characterization of the Initial Phase III Trial results as "Not Successful," were communicated to MPI through a September 2, 2014 e-mail to which was attached a letter dated August 29, 2014 from Ari Kellen ("Mr. Kellen"), an Executive Vice President and Company Group Chairman of Valeant.

Dispute Resolution Period in the Agreement

88. The Agreement contains a Dispute Resolution provision, § 13.12, which requires officers of both parties to attempt to resolve disputes through discussion. If the officers are unable to resolve the dispute within thirty days after the date written notice of the dispute is delivered, either party may seek any such remedy at law or in equity it deems necessary. Agreement, § 13.12. The parties have attempted to resolve the dispute but have been unable to do so.

89. Mr. Kellen of Valeant invoked the Dispute Resolution provision in the Agreement

on behalf of B+L in a letter dated September 9, 2014.

90. During the Dispute Resolution Period, B+L took the position that the final FDA Meeting Minutes were not specific to the Initial Phase III Trial when the FDA agreed that the exploratory sign and symptom endpoints assessed during the Initial Phase III Trial could be used as primary sign and symptom endpoints for Product Approval in an Additional Trial.

91. B+L also took the position that MIM-D3 did not demonstrate any signs of efficacy during the Initial Phase III Trial, and that B+L would not have obligated itself to pay $20 million or fund an Additional Trial if the Product did not demonstrate efficacy during the Initial Phase III Trial. Of course, this position is at odds with the plain language of the Agreement requiring, in relevant part, that "Not Successful" means "the FDA does not agree that either a sign or a symptom, that were assessed in the Initial Phase III Trial or the Additional Trial, can be used as the primary sign or symptom to support the Approval of the Licensed Product." Agreement, § 1.41.

92. The definition of "Not Successful" in the Agreement does not require indications of efficacy in the Initial Phase III Trial. During negotiation of the Agreement, B+L and MPI discussed the fact that the preliminary indication from the Initial Phase III Trial might not demonstrate efficacy based on their understanding of prior clinical trials for Restasis®, and they carefully negotiated and structured the Agreement so that Additional Trials would either continue with B+L's participation, or be funded with the $20 million termination fee if B+L elected not to exercise or extend the Option, regardless of whether the Initial Phase III Trial demonstrated the Product's efficacy.

93. In an October 28, 2014 letter to B+L, MPI expressed its dissatisfaction with the outcome of the attempt to resolve the dispute and provided B+L with a timetable and milestones

for reaching a resolution of the dispute between the parties, with the final item being that MPI would file a lawsuit against B+L for breach of the Agreement if a settlement was not achieved by December 1, 2014.

94. On November 13, 2014, while MPI was still actively attempting to negotiate a resolution to the dispute, B+L filed this preemptive declaratory judgment action in the Western District of New York, a venue with scant, if any, connection to the facts and circumstances underlying the dispute between the parties, apart from the fact that Plaintiff B+L has its corporate offices in the district.

95. Most of the calls, conference calls, and e-mails between MPI and B+L regarding the negotiation of the Agreement were done through MPI USA, and Directors of MPI, both in Massachusetts. To the extent that there were meetings in connection with the negotiation of the Agreement which did not take place in Massachusetts, those meetings took place in New Jersey, not New York.

COUNT I
(Breach of Contract against B+L)

96. MPI repeats and realleges the allegations set forth hereinabove as if set forth fully herein.

97. B+L has materially breached its contract with MPI by failing to pay MPI the $20 million due pursuant to § 5.5(c) of the Agreement, because it elected not to exercise or extend the Option after "Inconclusive" Initial Phase III Trial results.

98. In addition to the $20 million in damages due pursuant to § 5.5(c) of the Agreement, MPI suffered lost profits, consequential damages, and loss of its enterprise value as a direct and proximate result of B+L's breach of contract and the indefinite delay in the development of MIM-D3 said breach has caused.

COUNT II
(Intentional Breach of Contract Against B+L)

99. MPI repeats and realleges the allegations set forth hereinabove as if set forth fully herein.

100. B+L, with its extensive experience and sophisticated knowledge of the pharmaceutical industry and clinical trials, knew that there was no justification for contending that the Initial Phase III Trial yielded a "Not Successful" result.

101. It was more than apparent to B+L that the FDA approved the use of an exploratory sign and symptom endpoints from the Initial Phase III Trial as primary sign and symptom endpoints for use in Additional Trials. B+L knew that this is more than what was required for the Initial Phase III Trial to be considered not "Not Successful" under the Agreement (since only an exploratory sign or symptom endpoint is required by the Agreement)if there were no safety issues flagged by the FDA.

102. B+L never disputed that the FDA raised no safety issues with the Product. But despite its knowledge that the results of the Initial Phase II Trial were "Inconclusive," B+L decided to breach the Agreement.

103. The B+L team was enthusiastic about the results of the Initial Phase III Trial after the data were delivered to them on May 12, 2014. B+L proceeded to participate in designing an Additional Trial for MIM-D3 and never indicated to MPI any view that the results were "Not Successful" until after the Option period expired.

104. B+L breached the Agreement intentionally and in bad faith. Acting on behalf of Valeant, B+L breached the Agreement for, among other things, the purpose of destroying MPI's reputation and enterprise.

105. In light of Valeant's intended acquisition of Allergan, there existed a scheme on the part of B+L and Valeant to, among other things, injure MPI, the Product, and MPI's reputation so that Valeant gained a substantial benefit.

106. MPI suffered lost profits, consequential damages, and loss of its enterprise value as a direct and proximate result of B+L's intentional breach of contract, as well as the indefinite delay in the development of MIM-D3 said breach has caused.

COUNT III
(Intentional Interference with Contract Against Valeant)

107. MPI repeats and realleges the allegations set forth hereinabove as if set forth fully herein.

108. There is a valid contract between MPI and B+L of which Valeant was aware at all relevant times.

109. Valeant played a pivotal role in B+L's decision to breach the Agreement. Valeant induced B+L to breach the Agreement with the specific intent to cause harm to MPI's MIM-D3 development efforts in order to, among other things, damage a competitor to Allergan's Restasis®.

110. Valeant is a company known for acquiring pharmaceutical companies and slashing research and development expenses post-acquisition, and there was a specific motive for Valeant to insist that B+L dispense with MIM-D3. In addition, because Valeant was in the process of acquiring Allergan, it had no need for MIM-D3 since it was about to add Restasis® to its portfolio of products.

111. Upon information and belief, B+L regularly reported to Valeant on the status of the Initial Phase III Trial and the Agreement. At all times, Valeant executive management, specifically J. Michael Pearson, Valeant's Chief Executive Officer, exercised domination and

control over B+L with respect to B+L's misconduct in intentionally breaching the Agreement, and its falsely contending that the Initial Phase III Trial was "Not Successful," and refusal to pay the $20 million termination fee B+L was obligated to pay to MPI in connection with B+L's failure to exercise or extend the Option.

112. Valeant procured B+L's breach of the Agreement without any justification in contending that the results of the Initial Phase III Trial were "Not Successful." This served Valeant's goal of, among other things, disabling a competitor to Restasis®, a lucrative new product Valeant was convinced it would soon add to its product portfolio through its aggressive hostile takeover strategy in concert with Pershing Square.

113. As a result of Valeant's intentional interference with MPI's Agreement with B+L, MPI has suffered lost profits, consequential damages, and loss of its enterprise value as the direct and proximate result of Valeant's tortious and intentional interference with B+L performance under the Agreement, and the indefinite delay in the development of MIM-D3 said acts have caused.

COUNT IV
(Violations of M.G.L. c. 93A against Valeant)

114. MPI repeats and realleges the allegations set forth hereinabove as if set forth fully herein.

115. At all relevant times hereto Valeant was engaged in trade or commerce.

116. MPI is entitled to bring action under § 11 of the Consumer Protection Act, Mass. Gen. L. c. 93A, § 11.

117. MPI has been injured as a direct and proximate result of Valeant's use, in the conduct of trade or commerce, of the methods, acts, or practices described in Counts II and III

above, which methods, acts, or practices have been declared unlawful by Mass. Gen. L. c. 93A, § 2 or regulations issued thereunder.

118. The unfair and deceptive acts and practices alleged in this Count IV include but are not necessarily limited to the misconduct alleged hereinabove.

119. Valeant's actions and transactions constituting the unfair competition and unfair and deceptive practices, through its domination and control of B+L in respect of all facets of the relationship with MPI after Valeant's acquisition of B+L, occurred primarily and substantially within the Commonwealth of Massachusetts. Specifically, upon information and belief, senior B+L employees involved in the Initial Phase III Trial activities were reporting directly to J. Michael Pearson, Valeant's Chief Executive Officer, concerning the Initial Phase III Trial, the Option, and the Agreement. In addition, Mr. Kellen, a senior Valeant executive who reports directly to Mr. Pearson, was personally responsible for terminating the Option and taking the position that the Initial Phase III Trial was "Not Successful" in correspondence with MPI's Chief Executive Officer. Valeant pursued this course of misconduct, among other reasons, in order to undermine MPI's franchise and development of MIM-D3 since MPI was a direct competitor with Restasis®, a lucrative product with a virtual monopoly over the market for the treatment of dry eye syndrome, sold by Valeant's acquisition target, Allergan.

120. As a result of Valeant's unfair and deceptive conduct, MPI suffered damages.

121. MPI is therefore entitled to judgment (including its actual damages, costs, and attorneys' fees) against Valeant on this Count IV.

122. Because the methods, acts or practices described in this Count IV constituted willful or knowing violations of Mass. Gen. L. c. 93A, § 2, MPI is entitled to treble, and not less than double, damages in the captioned action against Valeant.

WHEREFORE, MPI respectfully requests that the Court:

(a) Enter a judgment against B+L in the amount to be determined at trial;

(b) Enter a judgment against Valeant in the amount to be determined at trial;

(c) Award treble damages pursuant to Mass. Gen. L. c. 93A, § 11;

(d) Award MPI its costs, expenses and attorneys' fees incurred in this matter;

(e) Award MPI exemplary, punitive and multiple damages against B+L and Valeant for their tortious conduct;

(f) Award MPI pre-judgment and post-judgment interest; and

(g) Grant such other and further relief as this Court deems just and appropriate.

JURY DEMAND

Counterclaim Plaintiff demands a jury trial on all issues so triable.

Dated: January 30, 2015

Respectfully submitted,

MIMETOGEN PHARMACEUTICALS INC.

By its attorneys,

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CERTIFICATE OF SERVICE

I hereby certify that a true copy of this Answer with Affirmative Defenses, Counterclaims and Third Party Claims was served upon all counsel of record, electronically through the CM/ECF system on January 30, 2015.

By: /s/ Travis M. Tatko
Travis M. Tatko